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Should hospitals invest in customised on-demand 3D printing for surgeries?

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Published in:
International Journal of Operations and Production Management

DOI (link to publication from Publisher):
10.1108/IJOPM-05-2020-0277

Publication date:
2020

Document Version
Accepted author manuscript, peer reviewed version

Accepted for publication in International Journal of Operations and Production Management

DOI (10.1108/IJOPM-05-2020-0277)

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Abstract

Methodology

The research design included interviews, workshops, and field visits. Design Science approach was used to analyse the impact of the 3D Printing (3DP) interventions on specific outcomes and to develop frameworks for hospitals to invest in 3DP, which were validated through further interviews with stakeholders.

Purpose

The purpose of this research is to 1) analyse the effect of customised on-demand 3DP on surgical flow time, its variability, and clinical outcomes 2) provide a framework for hospitals to decide whether to invest in 3DP or to outsource.

Findings

Evidence from this research shows that deploying customised on-demand 3DP can reduce surgical flow time and its variability while improving clinical outcomes. Such outcomes are obtained due to rapid development of the anatomical model and surgical guides along with precise cutting during surgery.

Research implications

We outline multiple opportunities for research on supply chain design and performance assessment for surgical 3DP. Further empirical research is needed to validate the results.

Practical implications

The decision to implement 3DP in hospitals or to engage service providers will require careful analysis of complexity, demand, lead-time criticality and the hospital's own objectives. Hospitals can follow different paths in adopting 3DP for surgeries depending on their context.

Originality value

The operations and supply chain management community has researched on-demand distributed manufacturing for multiple industries. To the best of our knowledge, this is the first paper on customised on-demand 3DP for *surgeries*..

1. Introduction

A patient with an advanced-stage tumour in the tibia risks losing his leg. Surgeons, doing orthopaedic oncology surgeries, typically maintain higher margins of safety and thus, cut more portions of the bone than needed. Cutting healthy bones around the tumour makes recovery longer and more difficult. Fortunately, 3D printed anatomical models of the bone and tumour, and patient-specific surgical guides, using a digital design process, help in removing the tumour accurately. Thus, the patient's recovery is expedited. This is not an isolated case. Approximately 600 such surgeries have been conducted since 2016 in the Sourasky Medical Center in Tel-Aviv, Israel. 33 hospitals run by the US Department of Veterans Affairs also have 3D printers (Apte, 2020). The confidence in the safety and efficacy of 3DP processes for surgeries has accelerated in recent years (Diment et al., 2017).

Apart from the medical success stories, what could operations management (OM) researchers learn from it? To derive insights, we address the following questions: 1) how can customised design and 3D printed anatomical models, implants, and surgical instruments impact flow time, its variability and other clinical outcomes? 2) how can hospitals take decisions regarding investment in 3DP for surgical purposes?

The operations management literature has focused on 3DP applications primarily for industrial (Holmström et al., 2019; Roscoe et al., 2019) and pharmaceutical (Roscoe and Blome, 2019) manufacturing, with no study till date on surgical applications. Holmström et al. (2019) identified redistribution of activities and interactivity of the digital artefact in the process as the pathways enabled by 3DP. Yet, such pathways have not been interpreted or analysed in the context of surgical processes.

2. Theoretical background

Design science allows researchers to be actively engaged in problem solving, while still developing scientific contributions. It helps in explicitly developing an 'artifact', which can be a decision making tool or a framework (Holmstrom et al., 2009). Context-Intervention-Mechanisms-Outcome (CIMO) logic in design science describes "what is done" (Intervention), in which situations (Context), to produce what effect (Outcome), and explaining why this happens (Mechanisms) (Denyer et al., 2008, p. 396). As the objective of this research is to address the decision making problem faced by hospitals regarding whether and how they should invest in 3DP, we adopted the design science approach to develop decision making frameworks for how to be invest in 3DP and to explain how interventions using 3DP can improve surgical outcomes

3. Methodology

We conducted 12 interviews (three rounds each) with four professionals (CEOs and Technical Managers of two 3DP service providers in Israel): One providing services related to segmentation, anatomical modelling, and manufacturing of patient-specific instruments

(Synergy3DMed[1]), another, focusing on manufacturing of customised implants (Kanfit3D[2]). We also conducted two interviews (CEO of a medical 3DP service provider in India, Anatomiz3D[3]). Israel's and India's healthcare systems differ and provide us with the opportunity to study two different contexts. Israel has a few dominant government hospitals and overall low to moderate surgery volumes. India has a large number of private hospitals along with government and charitable ones, and is typically characterised by high volumes of surgeries per hospital. The above service providers were leading companies with extensive experience in surgical 3DP (in Israel, the first with 396 procedures in 16 departments in one hospital, the second with 460; in India, over 1000 procedures).

The initial interviews, all transcribed, helped us understand the digital processes, the stakeholders involved, how to reduce the flow time and its variability and improve other clinical outcomes. In the follow-up interviews, we analysed the rationale for hospitals to invest in 3DP. We collected secondary data and archival material from the companies. We conducted field visits to the 3DP service providers and a hospital in Israel and organised two workshops involving surgeons and 3DP professionals: in the first workshop, participants shared their challenges. In the second, they shared solutions that are being implemented in practice to improve surgical flow time and clinical outcomes using 3DP. The notes from the interviews, field visits, and workshops were coded by two of the authors and validated by the others to specify the context, intervention, mechanisms, and outcomes. Emphasis was placed on understanding how 3DP intervention influenced the outcomes.

Finally, we followed the step of solution incubation to develop frameworks, which were further validated by interviewing the 3DP service providers and surgeons.

4. Analysis of the surgical process and outcomes

The process for developing customised on-demand 3DP of anatomical models and patient-specific instruments (PSI) starts with converting a Computerised Tomography (CT)/Magnetic Resonance Imaging (MRI) scan to a 3D model. This is followed by image segmentation[4], pre-surgical planning using the anatomical model, printed PSI , printed implant (if needed) and, finally, conducting the surgery. "*To ensure that the implant will fit in the right place, you need to design a PSI that will guide the saw and bring the pre-planning from a computer model to the actual patient. Using the cutting plane finalised by me, the service provider designs and 3D prints the PSI and thus I am able to cut in the exact dimensions, size and location that the implant will fit in*."-leading orthopaedic oncology surgeonfrom Israel.

The digital process enables the distribution of tasks among different members of the value chain. The customised 3D anatomical model (printed or digital) is the artefact that plays a significant role in (1) allowing those members to interact, (2) supporting planning and facilitating decision making during the surgery, if needed.

Error! Reference source not found. Table 1 presents the CIMO framework applied to the process of the orthopaedic oncology.

[1] http://synergy3dmed.com/
[2] http://www.kanfit3d.com/
[3] https://anatomiz3d.com/
[4] Image segmentation is a process of converting the 2D pixels of an image into 3D voxels

Table 1: CIMO analysis of 3D printed anatomical models, surgical guides, and instruments

<table>
<tr><td>Context (process before implementing 3DP):
CT and MRI files not merged
Surprises at the surgical table often requiring additional operations
Cutting excess bone
Long surgery time
Long recovery time</td></tr>
<tr><td>Intervention:
Surgeon or service provider segments/merges CT and MRI files
3D printed anatomical model for planning and surgery
Patient-specific 3D printed surgical guides and instruments</td></tr>
<tr><td>Mechanisms for:
Reducing flow time for the surgical process
Rapid development of the anatomical model
Improved understanding of the anatomy of the patient by the surgical team
Surgical planning using the 3D printed customised anatomical model
Swift development of the customised surgical guides and implants
Reducing variability in clinical outcome
Determining the exact location and length of the portion to be cut using the patient-specific anatomical model
Precise cutting using the patient-specific surgical guides and instruments</td></tr>
<tr><td>Outcomes:
Reducing flow time and its variability (diagnosis, surgery and recovery)
Reducing the time from recommendation for surgery to surgery date
Surgeries with durations of 4-8 hours become 1.5-2.5 hours shorter if patient specific instruments are used and 25-30 minutes shorter if only an anatomical model is used to plan the surgery
Reducing variability in clinical outcome
Improved predictability of surgical outcome for patient and surgeon
Lesser anaesthesia usage and related risks
Less bone is removed
Shorter recovery time for patients (e.g. a patient is able to walk 1-2 days after surgery compared to 3-4 days before)</td></tr>
</table>

5. How can hospitals decide whether to invest in in-house 3DP or to outsource the service?

The results from the second round of interviews, notes from the second workshop, and the field visit to the hospital, helped in identifying the relevant factors and in developing the decision-making framework presented below.

Hospitals need to consider complexity of the surgical planning process, lead-time criticality, annual demand, and prioritisation of hospitals' objectives. Complexity concerns the extent of involvement of the members of the surgical team in the 3DP process. Lead-time criticality captures the time between diagnosis and surgery. Annual demand for specific surgeries dictates volume. Prioritisation relates to two objectives: conducting more surgeries and developing expertise in the digitalisation of healthcare processes.

We provide two frameworks to aid hospitals in their decision making to invest in 3DP. Framework 1 (Figure 1) captures the dimensions of *complexity of surgical planning* and *lead-time criticality*. Framework 2 (Figure 2) captures the dimensions of *annual demand* and *prioritisation of objectives*. The frameworks demonstrate the redistribution of activities in the context of surgeries.

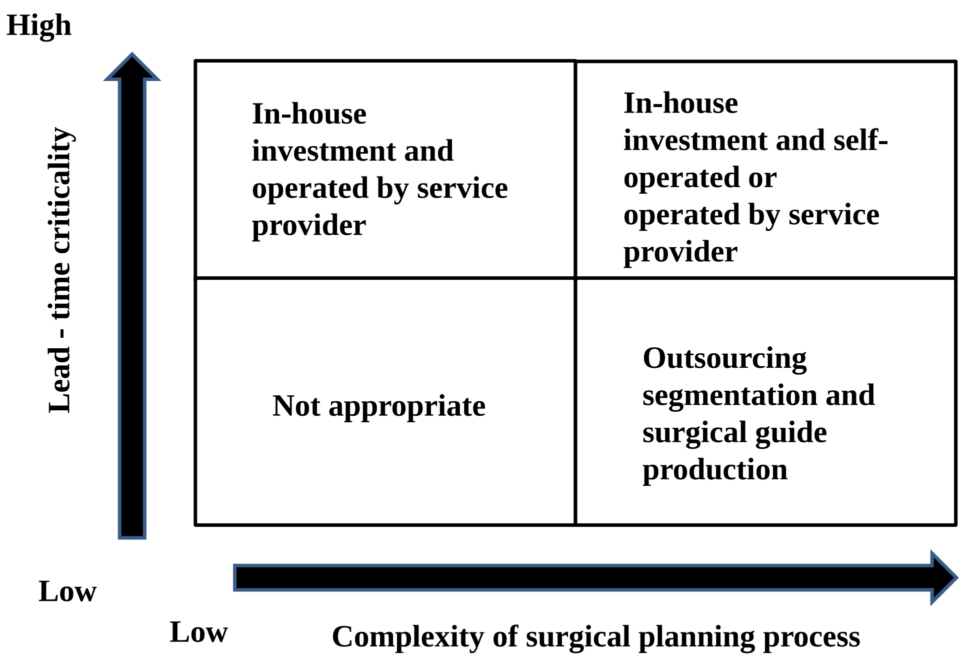

Figure 1: Framework 1 for hospitals' investment in 3DP

In Figure 1, for low values of both dimensions, applying digital processes may not be needed. Conversely, if both are high, hospitals should consider investing in developing in-house capabilities and nurturing internal expertise, thus saving time and transaction costs associated with interacting with service providers. This is corroborated by the Professor and Chair of Oral and Maxilofacial Surgery at a leading hospital in Israel: "*We have many trauma cases and time is limited. That's why in our Point-of-Care 3D Printing Lab, we have ensured that junior resident doctors are trained in segmentation, anatomical modelling and design of surgical guides or PSIs. Thus, we can respond to the needs ourselves while the service provider helps by printing the PSI.*"

If developing such in-house expertise to manage the day-to-day operations is not possible, hospitals may have to use the service provider to operate and manage the 3DP facility located within the hospital. *"A multi-specialty or super-specialty hospital conducts many complex surgeries with long durations. They will like to reduce the surgery time to accommodate more surgeries, explore different ways of conducting surgeries and also provide opportunities to junior surgeons to gain experience faster and shorten their learning curves by being involved in surgeries using 3DP. Hence, such hospitals are opting to invest in Point-of-Care 3DP* *facility operated by a service provider like us while we take inputs from the surgical team."*- Co-Founder and CTO of a leading Medical 3DP service provider in India.

If the complexity of surgical planning is high, but lead-time criticality is low, i.e., the surgery is not urgent, segmentation and surgical guide production can be outsourced. Using the segmentation, the surgical team may wish to print an anatomical model themselves to plan the surgery or conduct virtual surgical planning, as the complexity is high. Finally, if the complexity of surgical planning is low, but lead-time criticality is high, hospitals may entrust a service provider to operate and manage the facility within the hospital.

The estimated annual demand for the surgeries and how the hospitals prioritise their objectives will also influence the decision (Figure 2). If annual demand is high, the hospital may consider investing in the printers but allow a service provider to operate and manage them. This will ensure that the surgical teams can continuously interact with the service provider in-house and plan the surgeries efficiently and in shorter time. If annual demand is high and the hospital wants to develop internal expertise and position itself as a centre of excellence on digital innovation in healthcare, in-house investment and operation by an internal team may be considered. But a corporate hospital with a high volume of self-paying and insured patients may consider contracting a service provider that will invest, operate and manage the facility. Thus, the type of hospital and its objectives will influence the decision. If annual demand is low, but the hospital wishes to acquire new expertise and position itself as a centre of excellence, it may develop internal capabilities in segmentation (which is also getting automated by use of artificial intelligence) and anatomical modelling while outsourcing the surgical guide and implant production. Typically, outsourcing of 3DP metal implants is necessary due to regulatory requirements. Hospitals with low annual demand but expected to conduct more surgeries may outsource the 3DP processes. Hospitals may also have a phased approach and dynamically decide to increase their investment and involvement over time. *"We do see this as a question of maturity. Initially hospitals may involve us for specific surgical cases and once they experience the benefits and the surgeons get comfortable with analysing a 3D model and how to plan surgeries with it, they will like to do more types of surgeries. We have seen surgeons come up with their own ideas of how 3DP can be used for their specialties"*- Co-Founder and CTO of a leading Medical 3D printing service provider in India.

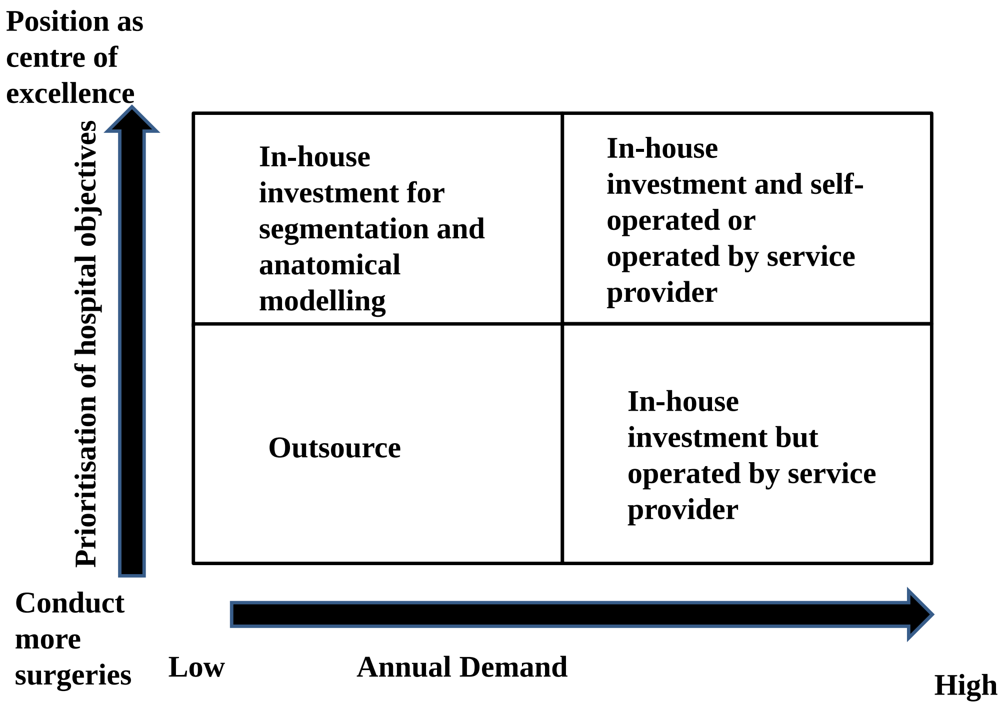

Figure 2: Framework 2 for hospitals' investment in 3DP

6. Future research directions and pathway to impact

In this section, we outline future research questions and identify potential methods to address those questions. We also provide pathways for scholarly research in Operations and Supply Chain Management for the domain of surgical 3DP.

Performance assessment

A relevant future research question can be: *How can the efficacy of 3DP versus the traditional process be quantitatively demonstrated and continually monitored?*

Performance measures should include: (1) hospital efficiency measures, e.g., surgery time, (2) clinical outcomes, e.g., volume of blood loss, and (3) patient satisfaction measures, e.g., time for recovery. In-depth case studies of surgeries using both conventional and digital processes can be conducted and performance measures can be compared while controlling for patient characteristics and level of complexity in the surgeries. Simulation models can be used to assess potential outcomes for investments in 3DP for surgical processes while considering learning effects. Developing cost of adoption models of 3DP processes in hospitals based on lifecycle costing principles, also including clinical outcome benefits, will be required. Our proposed frameworks also need to be validated and refined for different combinations of lead-time criticality, annual demand, complexity, and objectives for different types of hospitals.

Supply Chain Configuration Design

Designing the optimal supply chain configuration for the 3DP surgical process is needed to achieve the efficiency and the clinical outcomes.

The relevant research question is :

Which supply chain configuration will be suitable for which type of hospital and for which type of surgeries?

- *Fully outsourced (to an AM service provider)*
- *Fully in-house*
- *In-house but operated by the service provider*

In-depth case studies with simulation of the processes and optimization of the network can be done to address the above question. In this context, as demonstrated by Srai et al. (2020), the role of the supply network which consists of key supply units, operating across the supply chain, needs to be studied.

Similarly, supply chain integration for customised on-demand 3DP for surgeries needs to be defined. Design of the patient-specific instrument by a surgeon and a designer is a unique phenomenon. Whether and to what extent surgeons and hospitals should demonstrate such ambidextrous capability (Roscoe et al., 2019) in terms of being involved in both the digital and the clinical process is an important question which needs to be answered. Similarly, further work is needed to analyse and quantify the impact of redistribution of activities and interactivity of the anatomical model as a digital artefact for the surgical process as outlined by Holmström et al. (2019).

Research on operations and supply chain implications of 3DP is in nascent stage and has focussed on industrial manufacturing and design as manufacturing industries like aerospace, automotive and medical devices were the earliest adopters of 3DP for prototyping, tooling and spare parts applications. As this research points out, there are interesting research questions which need to be addressed in the context of 3DP for surgeries related to performance management, supply chain configuration design and in managing the design-manufacturing-surgical process interfaces. Industry 4.0 research,as pointed out by Koh et al.(2019) and 3DP research in particular, is highly inter-disciplinary and requires deep understanding of the domain of application. Hence, supply chain management researchers are encouraged to create multi-disciplinary research projects involving researchers from engineering, biotechnology, medicine and also with colleagues researching innovation, technology management and policy to engage in impactful studies.

7. Conclusion

This is among the first articles presenting direct operational evidence of implementing of customised on-demand 3DP and discussing the decision-making challenges it poses for hospitals. We assessed the performance implications of customised on-demand 3DP for surgeries and outlined frameworks for hospitals to invest in 3DP. Following the guidelines outlined by van Aken et al. (2016), we developed the frameworks as an initial design, which answers the questions of whether and how hospitals should invest in 3DP. Finally, we outlined future research directions. Our research is expected to motivate scholars to conduct research on the operational and supply chain implications of 3DP for surgeries.

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